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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,268	09/29/2003	Michael Fantuzzi	33503/US	3101

7590 10/25/2007
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Intellectual Property Department
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Minneapolis, MN 55402-1498

EXAMINER

KOSSON, ROSANNE

ART UNIT	PAPER NUMBER
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1652

MAIL DATE	DÉLIVERY MODE
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10/25/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

10/674,268

Applicant(s)

FANTUZZI, MICHAEL

Examiner

Rosanne Kosson

Art Unit

1652

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED on Oct. 8 & 16, 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: _____.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☒ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see below.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____.
13. ☐ Other: _____.

The claims have not been amended.

The Declaration under 37 CFR §1.131 presented by Applicant has not been considered. Please refer to MPEP §714.13 wherein it is stated that new affidavits or other new evidence should not be entered unless Applicant provides "good and sufficient reasons" under 37 CFR § 1.116 or 37 CFR § 1.195 why they were not earlier presented.

With respect to Applicant's arguments, Applicant asserts that Erwin is not an enabling disclosure and therefore is not prior art. In reply, the relevant teaching from Erwin is that d-limonene is a solvent for co Q10 and a solvent that can be used to prepare nutraceutical compositions of co Q10. The provisional application filed on June 25, 2003 is enabled for this teaching and contains a working example on p. 3. Thus, Erwin is entitled to the priority of this filing date, which antedates the filing date of the instant application. Erwin does not disclose the maximum amount of co Q10 that can be dissolved in d-limonene. But that amount is an inherent property of both the solute and the solvent and is a property that could readily have been determined by one of ordinary skill in the art.

As for Applicant's result that he can prepare a 60% by weight solution of co Q10 in limonene, whereas only a 9% solution in soybean oil is possible, first, the rejection is that it would have been obvious to one of ordinary skill in the art at the time of the invention to replace the rice bran oil of Soft Gel with the d-limonene of Erwin, because Erwin teaches that co Q10 is soluble in d-limonene and that the limonene solution has better bioavailability than other formulations (delivers more of the co Q10 to cells). Folkers et al. are not part of the instant rejection. This reference was, however, cited in related cases in which the claims have the limitation that the co Q10-containing limonene solution comprises a carrier that may be soybean oil. It has been noted in Office actions in related cases that Folkers et al., i.a., are prior art over which Soft Gel sought to make an improvement.

Second, some of the claims do not recite a numerical range for the amount of co Q10 that is present. In the claims that do recite a numerical range, the largest range is 0.1-45% by weight (claims 36 and 46), while the claims with highest upper limit recite that 50% by weight of co Q10 is dissolved in limonene (claims 34 and 45). Thus, a 60% by weight solution is not required in any claim. Again, the rejection is that it would have been obvious to replace the rice bran oil of Soft Gel with the d-limonene of Erwin, and Applicant has not compared the solubility of co Q10 in these two solvents, nor has Applicant shown that different and surprising or unexpected results are achieved by using the claimed invention vs. any preparation of co Q10 in the prior art. The solubility of co Q10 in soybean oil is not the point.

As for Applicant's comment that one of skill in the art would not know from Erwin that co Q10 was more soluble in d-limonene than in the solvents of Folkers et al. or Soft Gel, again, Folkers et al. are not part of the rejection. Erwin teaches a 15% solution in the Example and ranges of 1-85%, 5-30% and 12-18% in the various embodiments (see paragraphs 10-30). Soft Gel teaches that its formulation contains 30 mg of co Q10, 30 IU of vitamin E and rice bran oil, although the volume of this formulation is not given. But, as noted above, some claims do not recite any quantity for the amount of co Q10 in the soft gel, while the claims that do recite lower limits of 10, 15, 5 and 0.1% by weight (see claims 18, 33, 34, 36, 43, 45 and 46). Erwin's working example teaches a 15% solution. Claims 32 and 42 recite a lower limit of 30% by weight, but Erwin's second embodiment, even if prophetic, recites a range of 5-30% by weight. Thus, one of ordinary skill in the art would have expected to have been able to make a 0.1-30% by weight solution of co Q10 in d-limonene.

On p. 9 of his response, Applicant continues to discuss Folkers et al. In the second paragraph on this page, Applicant refers to the portion of the previous Office actions that state that Soft Gel certainly implies a solution in rice bran oil, in reply to Applicant's assertion that Soft Gel discloses a suspension in rice bran oil. This point clearly pertains to the Soft Gel reference alone, yet Applicant discusses Folkers et al. and fish oil. Applicant notes that if Folkers et al. could produce an emulsion, a suspension in fish oil is not surprising. Applicant appears to be confusing three references, and his logic is not clear.

Regarding Davidson et al., Applicant again discusses Folkers et al. Davidson et al. are relevant to claims 40 and 50, which recite that the soft gel comprises co Q10 dissolved in limonene and further comprises a carrier, the carrier being fish oil. To reiterate from previous Office actions, the claims do not recite that the co Q10 is dissolved in the fish oil. Applicant asserts that Davidson et al. do not explicitly recite a solution of co Q10 in fish oil. As previously discussed, a solution is implied, one of ordinary skill in the art would have expected to have been able to dissolve co Q10 in the fish oil (because co Q10 is soluble in oils but not in water or hydrophilic solvents), and the claims do not require this solution.

In view of the foregoing, the rejection of record is maintained.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is 571-272-2923. The examiner can normally be reached on Monday-Friday, 8:30-6:00, alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Rosanne Kosson
Examiner, Art Unit 1652



rk/2007-10-18

/Rebecca Prouty/
Primary Examiner
Art Unit 1652